Handheld Doppler
Is it safe for my baby?

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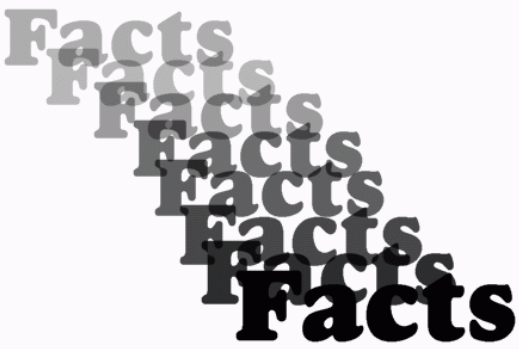
"Fetal Dopplers Are Regulated By The FDA And Are Approved For Personal Use With The Approval Of Your Physician. Research Has Proven That The Waves From A Doppler Will Not Harm An Unborn Baby. Be Sure To Contact Your Physician Before Using A Fetal Doppler Monitor.

The Unit Retailed Through Stork Radio For $449.00"

eBay, accessed 2/27/06



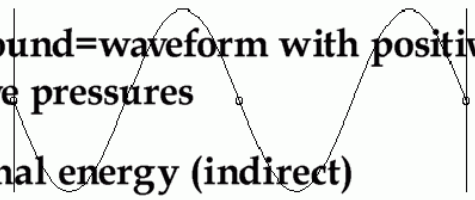
Facts

Ultrasound* is energy

* in any form

Ultrasound= Energy

Ultrasound=waveform with positive and negative pressures



Thermal energy (indirect)

Mechanical energy (direct): positive pressure causes movements, negative pressure can induce cavitation

Ultrasound= energy

In tissues it traverses it will cause:

1. ↑ heat (thermal effect)
2. oscillatory movements (mechanical effect:cavitation,shear, streaming, free radicals)

Facts

Ultrasound (under certain conditions) can heat tissues.

(Therapeutic: 1MHz, 4-5 W/cm^2)

Facts

Heating of tissues by ultrasound is very fast: 1-2 minutes from onset of exposure (30 seconds near bone)

Measures of intensity

- I_{SPTP} : maximum intensity w/ respect to space and time
- I_{SPPA} : pulsed averaged intensity at spatial peak (averaged over pulse duration)
- I_{SPTA} : at SP, averaged w/ sound on & off
- I_{SAPA} : average intensity w/ sound on, during pulse
- I_{SATA} : average intensity in a beam over time

Maximal allowed intensity for fetal ultrasound

94mw/cm^2

720mw/cm^2

Acoustic power measurements of Doppler ultrasound devices used for perinatal and infant examinations.
Rabe et al., Pediatr Radiol, 1990

"...Each of the four devices was tested while running in its commonly used mode, and comparison showed that their acoustic power values varied widely: 96.8 mW (2 MHz, EME TC2-64B), 8.7 mW (5 MHz, ATL Mk 500), 61.9 mW (3.5 MHz, Acuson 128) and 13.5 mW (5 MHz, HP 77020)..."

A survey of the acoustic output of ultrasonic Doppler equipment.
Duck et al., 1987

Measurements of the acoustic output generated by a variety of clinical ultrasonic Doppler instruments: continuous wave Doppler units , fetal monitors, stand-alone pulsed Doppler equipment and 'duplex' scanners working in Doppler mode

"...Almost all the pulsed Doppler and duplex systems investigated could generate spatial-peak, temporal-average intensities in water which exceeded 100 mW/ cm^2, with a maximum of 825 mW/ cm^2 measured . These intensities were also reached by some continuous-wave Doppler systems...Doppler units have been found to show a very wide variation in pulse length, repetition frequency and spatial peak pressure, and a wider range of pulse average intensities than previously reported..."

Barnett SB, Maulik D; International Perinatal Doppler Society :
Guidelines and recommendations for safe use of Doppler ultrasound in perinatal applications. J Matern Fetal Med. 2001;10:75-84.

When modern sophisticated equipment is used at maximum operating settings for Doppler examinations, the acoustic outputs are sufficient to produce obvious biological effects, e.g. significant temperature increase in tissue or visible motion of particles due to radiation pressure streaming effects.

The risk of inducing thermal effects is greater in the second and third trimesters, when fetal bone is intercepted by the ultrasound beam and significant temperature increase can occur in the fetal brain. Non-thermal bioeffects may be more significant in early gestation, when the relatively loosely tethered embryonic tissues are exposed to an ultrasound beam in a liquid path.

...To ensure the continued safe use of ultrasound in obstetrics, it is important that international ultrasound organizations... issue advice to members to allow sensible assessment of risk: benefit and the practical implementation of the ALARA (as low as reasonably achievable) principle.

Newnham JP et al., Lancet, 1993
Effects of frequent ultrasound during pregnancy: a randomised controlled trial

2834 singleton pregnancies
1415 with ultrasound and continuous Doppler exam at 18, 24, 28, 34, 38 weeks
1419 single scan at 18 weeks

"...The only difference between the two groups was significantly higher intrauterine growth restriction in the intensive group, when expressed both as birthweight < 10th centile and birthweight < 3rd centile...
While it is possible that this finding was a chance effect, it is also plausible that frequent exposure to ultrasound may have influenced fetal growth. Repeated prenatal ultrasound imaging and Doppler flow examinations should be restricted to those women to whom the information is likely to be of clinical benefit."

Unknowns

Length of exposure
Cumulative effect
Repeat injury

Duck FA: Is it safe to use diagnostic ultrasound during the first trimester (editorial): Ultrasound Obstet Gynecol 13:385, 1999

"...no epidemiological or other evidence was then [in the early 90's] or is now available to support the assertion of safety at these high exposures"

Research on the fetus using Doppler ultrasound in the 1st trimester: guiding ethical considerations.

Chervenak and McCullough
Ultrasound Obstet Gynecol, 2000

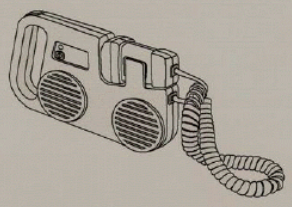
But do we know what is the actual acoustic output ("power") of Doppler devices?

How reliable are manufacturer's reported acoustic output data?

"...reported data are almost invariably an underestimate..."

Jago et al,
Ultrasound Med Biol, 1995

Heartbeats at Home
Fetal Doppler
User's Manual



SPECIFICATIONS (continued)

Global Maximum values are the maximum expected values based on statistical analysis of one production lot.
- $I_{spta.3}$ - The **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter).
- $I_{sppa.3}$ - The **derated spatial-peak pulse-average intensity** (watts per square centimeter).
- MI - The **mechanical index**.
- Pr - The **peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported for MI.
- W_o - The total time-average **ultrasonic power** (milliwatts).
- f_c - The probe **center frequency** (MHz).
- Z_s - The axial distance at which the reported parameter is measured (centimeters).
- X_{-6}, Y_{-6} - The -6 dB beam dimensions in the x-y plane where Z_s is found (centimeters).
- EBD - The entrance beam dimensions (centimeters). These dimensions are the same as the dimensions of the transmit crystal.

Operating Cond... which affect the ultrasound output.

Measurement Uncertainties:

Power	+29%, -42%
Pressure	+17%, -23%
Intensity	+18%, -29%
Frequency	±1...

Additional IEC1157 Requirements:
3MHz: This probe is excepted from ...abeling requirements of IEC1157 because the following inequalities are met:
Spatial-peak temporal-average intensity (I_{spta}) <100 mW/cm²
Output beam intensity (lob... 20 mW/cm²
Peak negative acoustic pressure (P) < 1MPa

Measurement Uncertainties:

Power +29%, -42%
Pressure +17%, -23%
Intensity +18%, -29%

There may be major differences between

1. once a month in Healthcare Provider's office

and

2. Every day (twice a day? five times a day?) at home

Thank you